



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0643; FRL-9920-45]

Sulfoxaflor; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of sulfoxaflor, *N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]- λ^4 -sulfanylidene]cyanamide, including its metabolites and degradates in or on sorghum, grain; sorghum, forage; and sorghum, stover. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sorghum. This regulation establishes a maximum permissible level for residues of sulfoxaflor in or on these commodities. The time-limited tolerances expire on December 31, 2017.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0643, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson

Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0643 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0643, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of sulfoxaflor, *N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]- λ^4 -sulfanylidene]cyanamide, including its metabolites and degradates in or on sorghum, forage at 0.40 parts per million (ppm); sorghum, grain at 0.30 ppm; and sorghum, stover at 0.90 ppm. These time-limited tolerances expire on December 31, 2017.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of

FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe”. Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Sulfoxaflor on Sorghum and FFDCA Tolerances

Numerous states requested emergency exemptions for the use of sulfoxaflor on sorghum to control sugarcane aphid (*Melanaphis sacchari*). Based on information provided by the states, this is either a new pest or new biotype of *M. sacchari*. There are no registered insecticides or economically or environmentally feasible alternative control

practices available to adequately control this non-routine pest infestation. Unusually high populations of aphids can cause direct plant death from aphid feeding as well as indirect damage and harvesting issues from the aphid honeydew residue. The states asserted that without the use of sulfoxaflor, uncontrolled aphid infestations are likely to result in significant economic losses.

After having reviewed the submissions, EPA determined that an emergency condition exists for these States, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of sulfoxaflor on sorghum for control of sugarcane aphid in Arkansas, Florida, Georgia, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and Texas.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of sulfoxaflor in or on sorghum. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2017, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sorghum after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that

application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether sulfoxaflor meets FIFRA's registration requirements for use on sorghum or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of sulfoxaflor by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than those authorized to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for sulfoxaflor, contact EPA's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of sulfoxaflor in or on sorghum, forage; sorghum, grain; and sorghum, stover. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

EPA has evaluated this use of sulfoxaflor on sorghum, as well as its use on various other crops, and established tolerances for similar use patterns in the **Federal Register** of May 17, 2013 (78 FR 29041) (FRL-9371-4) in association with requests for tolerances to support registrations of sulfoxaflor under FIFRA section 3 .

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for residues of sulfoxaflor in or on sorghum, forage at 0.40 ppm; sorghum, grain at 0.30 ppm; and sorghum, stover at 0.90 ppm. There is an existing permanent tolerance for sulfoxaflor residues in/on aspirated grain fractions at 20 ppm and that tolerance is sufficient to address residues in/on aspirated grain fractions that may come from sorghum. In addition, sorghum commodities may be used as livestock feedstuffs. Inclusion of sorghum in the estimated reasonable balances livestock dietary

burdens for cattle, poultry, and swine did not result in a need for revision of the existing tolerances for residues of sulfoxaflor in livestock commodities.

In the May 17, 2013 **Federal Register**, EPA published a final rule establishing tolerances for residues of sulfoxaflor in 40 CFR 180.668 in or on numerous commodities. A summary of the toxicological endpoints for sulfoxaflor for human risk assessment is discussed in Units III.A. and B. of the May 17, 2013 **Federal Register** final rule.

In evaluating dietary exposure, the Agency has noted that estimated drinking water concentrations based on the sulfoxaflor use on sorghum resulted in lower estimates than those previously assessed and the food consumption database used to support the Agency's dietary exposure assessments does not report any consumption of sorghum, either as grain or as syrup. Therefore, the dietary exposure estimates from the previous assessment are not changed by the FIFRA section 18 use. Dietary risk estimates from exposure to sulfoxaflor through food and water are below the Agency's level of concern.

In its aggregate assessment of exposures and risk associated with sulfoxaflor, EPA concluded the following: Acute dietary exposure from food and water to sulfoxaflor will occupy 16% of the acute population adjusted dose (aPAD) for children 1-2 years old and females 13-49 years old, the population groups receiving the greatest exposure; and chronic exposure to sulfoxaflor from food and water will utilize 18% of the chronic population adjusted dose (cPAD) for all infants, the population group receiving the greatest exposure. These estimates are well below 100% and are, therefore, below the Agency's level of concern.

There are no residential uses of sulfoxaflor at this time. Consequently, aggregate exposure and risk estimates are equivalent to the dietary (food + drinking water) exposure and risk estimates discussed in this unit.

Therefore, EPA concluded there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to sulfoxaflor residues.

Refer to the May 17, 2013 **Federal Register** final rule, available at <http://www.regulations.gov>, for a summary of the aggregate risk assessment and determination of safety. Detailed discussion of the aggregate risk assessments and the determinations of safety relied upon in this action may be found in the Agency reviews and human health risk assessments provided as supporting documents in the docket for this action (EPA-HQ-OPP-2014-0643).

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology is available to enforce the tolerance expression. In the submitted field trials, residues of sulfoxaflor and its metabolites in crops were determined using the Dow analytical method designated as 091031. The proposed method for tolerance enforcement in plant commodities is method 091116: “Enforcement Method for the Determination of Sulfoxaflor (XDE-208) and its Main Metabolites in Agricultural Commodities Using Offline Solid-Phase Extraction and Liquid Chromatography with Tandem Mass Spectrometry Detection.” Method 091116 extracts residues with acetonitrile/water and includes use of a deuterated internal standard, hydrolysis with sodium hydroxide to release base-labile conjugates, and clean up via solid-phase extraction. This method is applicable for the quantitative

determination of residues of sulfoxaflor, *N*-[methyloxy[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]- λ^4 -sulfanylidene]cyanamide and its metabolites, X11719474, *N*-((methyl)oxido[1-[6-(trifluoromethyl)pyridine-3-yl]ethyl]- λ^4 -sulfanylidene)urea and X11721061, 1-[6-(trifluoromethyl)pyridin-3-yl]ethanol, in agricultural commodities and processed products. The method was adequately validated, with a limit of quantitation (LOQ) of 0.010 milligram/kilogram (mg/kg) for all matrices, including sorghum. The Food and Drug Administration Multi-Residue Method was reported by the registrant to be not suitable for analysis of sulfoxaflor and/or its metabolites; the German multi-residue Method S-19 may be suitable.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for sulfoxaflor in/on sorghum commodities.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of sulfoxaflor, in or on sorghum, forage at 0.40 ppm; sorghum, grain at 0.30 ppm; and sorghum, stover at 0.90 ppm. These tolerances expire on December 31, 2017.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 15, 2015.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.668, revise paragraph (b) to read as follows:

§ 180.668 Sulfoxaflor; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of sulfoxaflor (*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]- λ^4 -sulfanylidene]cyanamide), including its metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the following table is to be determined by measuring only sulfoxaflor in or on the commodity. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Sorghum, forage	0.40	12/31/17
Sorghum, grain	0.30	12/31/17
Sorghum, stover	0.90	12/31/17

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